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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/039,260	03/16/98	ABERG A	4821-306

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EXAMINER	
CRANE, L	
ART UNIT	**PAPER NUMBER**
1623	7

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Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/039,260	Applicant(s) Aberg et al.
	Examiner L. E. Crane	Group Art Unit 1623

---The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ----3----- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 4/8/98 (IDS), 6/28/98 (AmdtA) & 9/16/98 (IDS#2) ----------.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-14 and 48-62 ---------- is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-14 and 48-62 ---------- is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

[x] Claims 15-47 have been cancelled.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 & 6-- ☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Acti n Summary

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

Claims **15-47** have been cancelled, new claims **48-62** have been entered and the preliminary amendments filed June 28, 1998 has been entered. Also, the Information Disclosure Statements (IDS's) filed April 8 and September 16, 1998 have been received and made of record.

Claims **1-14 and 48-62** remain in the case.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. §101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the same invention in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.,* 151 U.S. 186 (1894); *In re Ockert,* 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel,* 422, F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. §101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based on 35 U.S.C. §101.

Claims(s) **1-7** are rejected under 35 U.S.C. §101 as claiming the same invention as that of claim(s) ***1-7*** of prior U.S. Patent No. **5,595,997** (PTO-892 ref. **A**). This is a double patenting rejection.

Claims(s) **8-14** are rejected under 35 U.S.C. §101 as claiming the same invention as that of claim(s) *1-7* of prior U.S. Patent No. **5,731,319** (PTO-892 ref. **B**). This is a double patenting rejection.

Claims **1, 8 and 48-62** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **1 and 8**, line 5, and claims **54-59**, line 1, the acronym "DCL" is noted but has not been accompanied by a common or more preferably an IUPAC chemical name. Applicant is respectfully requested to identify by IUPAC chemical name all active ingredients with the acronym following in parentheses in the first independent claim where the compound is identified; |e.g. -- 3'-deoxy-3'-azidothymidine (AZT) --. Subsequent use of the acronym is then freely available.

In claims **48-62**, more particularly independent claims **48 and 54-59**, are incomplete because the term "pharmaceutical composition" is not accompanied within the noted independent claims by the term -- and a pharmaceutically acceptable carrier --. Should applicant adopt the instant suggested amendment to all of the independent claims, claim **51** would be rendered an improperly dependent claim and should be cancelled.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

Claims **48-54 and 60-62** are rejected under 35 U.S.C. §102(**b**) as being anticipated by Villani et al. (PTO-1449 ref. **AC**) wherein Berkow et al. (PTO-892 ref. **R**) is cited to provide the definition of a specific compound well known in the art to be a "decongestant" commonly used in binary pharmaceutical compositions in combination with an antihistamine.

In the Villani et al. reference at column 8, lines 42-46, the combination of DCL and an decongestant in a single pharmaceutical composition is generically taught. The Berkow reference discloses at p. 326 under the heading "Treatment," lines 1-6, in particular lines 4-6, the combination of an antihistamine with the decongestant "pseudoephedrine" in a single pharmaceutical composition. This teaching represents no more than an exemplification of the generic "antihistamine + decongestant" teaching in the Villani reference.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **48-54 and 60-62** are rejected under 35 U.S.C. §103(a) as being unpatentable over Villani et al. (PTO-1449 ref. **AC**) in view of Berkow et al. (PTO-892 ref. **R**).

Villani et al. discloses at column 8, lines 42-46, the combination of DCL and an decongestant in a single pharmaceutical composition is generically taught. This reference does not disclose pharmaceutical compositions wherein the specific decongestant has been specified.

Berkow et al. discloses at p. 326 under the heading "Treatment," lines 1-6, in particular lines 4-6, the combination of an antihistamine with the decongestant "pseudoephedrine" in a single pharmaceutical composition. This reference does not disclose pharmaceutical compositions wherein DCL and any one decongestant have been specified as the active ingredients.

The noted teaching of the Villani reference clearly motivates the ordinary practitioner to go out and find a decongestant to combine with DCL in a binary pharmaceutical composition. For this reason the instant claims are deemed to lack patentable distinction in view of the noted prior art references which do all but teach the specific combination active ingredients specified in claim **54**.

Therefore, the instant claimed binary pharmaceutical compositions comprising DCL and a decongestant, pseudoephedrine in particular, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Claims **55-62** are rejected under 35 U.S.C. §103(a) as being unpatentable over Villani et al. (PTO-1449 reference **AC**) in view of Gennaro et al. (PTO-892 reference **S**).

The instant claims are directed to pharmaceutical compositions comprising DCL and an analgesic selected from the group consisting of acetylsalicylic acid, acetaminophen, ibuprofen, ketoprofen and naproxen.

The Villani et al. reference at column 8, lines 42-46, the combination of DCL and "other therapeutic agents" in a single pharmaceutical composition of the kind found in claims ***5-8***, particularly claim ***5*** which is directed to "an antihistaminic pharmaceutical composition comprising ... [DCL] ... ." This reference does not teach the specific combination of DCL and an analgesic.

The Gennaro et al. reference discloses at p. 1131, column 2, numerous binary and trinary pharmaceutical compositions which contain antihistiminic activity and a mild analgesic, "acetaminophen" in particular being specified in the fourth, seventh and eighth compositions listed. Looking forward in the same reference, one finds beginning at p. 1109 an extensive listing of "Analgesics and Antipyretics" with the following compounds listed at the page in parentheses following each name:
i) acetylsalicylic acid (aka aspirin, p. 1110),
ii) acetaminophen (p. 1109),
iii) ibuprofen (p. 1116),
iv) ketoprofen (p. 1112) and
v) naproxen (p. 1118). At p. 1109, column 2, this references states concerning the complete listing of compounds which follows that "...

Most of these agents affect both pain and fever. Consequently they are used widely for minor aches and pains, headaches and the general feeling of malaise that accompanies febrile illness, ..." This reference does not teach the specific combination of DCL and an analgesic.

The teaching of the Villani et al. reference motivates the combination of the antihistamine DCL with other medicinal agents in binary pharmaceutical compositions of the kind specifically embodied at p; 1131 of the Genarro et al. reference. The substitution of DCL for an antihistamine and the substitution of a different mildly analgesic substance for acetaminophen are therefore deemed to have been variations well within the perview of the ordinary practitioner seeking to optimize the efficacy of the antihistiminic-analgesic binary composition when the antihistamine is DCL. And, while Villani does not specifically teach combinations of DCL with analgesics, the Gennaro reference makes plain by its examples and other teachings that such combinations are notoriously well known and accepted variations in the pharmaceutical composition art, and are widely used to treat mild allergy-related nasal congestion.

Therefore, the instant claimed antihistiminic pharmaceutical compositions comprising DCL and an analgesic selected from the group consisting of acetylsalicylic acid, acetaminophen, ibuprofen, ketoprofen and naproxen would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

References made of record but not cited above are deemed to be either equivalents to the cited references or to be of interest as

closely related prior art which shows the state of the relevant prior art.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592** .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639** . The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached at (703)-308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235** .

LECrane:lec
6/10/99

L. Eric Crane
Patent Examiner
Group 1600